

Appl. No. : 08/779,767
Filed : January 7, 1997

REMARKS

I. Interview of March 20, 2000

Applicant thanks the Examiner for extending the courtesy of a telephonic interview to Dan Hart on March 20, 2000. The substance of the interview is reflected in the foregoing amendments and the following remarks. Applicant notes that during the interview of March 20, 2000 the Examiner indicated that claims to compositions in which the T cell receptor antagonist is derived from proteolipid protein would be allowable in view of the unexpected results discussed below and in the accompanying Declaration of Habib Zaghouani.

II. Rejection of Claims 4, 6, 9, 11, 24, 26, 27, 29, 66-70 and 72-73 Under 35 U.S.C. §103

Claims 4, 6, 9, 11, 24, 26, 27, 29, 66-70 and 72-73 were rejected under 35 U.S.C. §103 on the assertion that they were obvious over the combination of Bona and Kuchroo. The Examiner asserts that Bona discloses immunoglobulins in which a viral peptide is inserted into the CDR3 region and that Kuchroo discloses the use of a T cell antagonist to treat an autoimmune disease. Accordingly, the Examiner asserts that the claimed invention is *prima facie* obvious over the cited combination of references.

As discussed in the interview of March 20, 2000, although Applicant does not concede that the claimed invention is *prima facie* obvious over the cited combination of references, Applicant notes that a *prima facie* assertion of obviousness may be overcome by a showing of unexpected results. As indicated by the Declaration of Habib Zaghouani submitted herewith, the claimed compositions, when administered to subjects suffering from an autoimmune disease, permanently eliminated the symptoms of the disease in all the subjects treated with the compositions. As indicated in the accompanying Declaration, although Applicant does not intend to be limited to a particular mechanism of action, Applicant believes that the claimed compositions permanently eliminate disease symptoms by permanently preventing replication of the pathogenic T cells.

As discussed below, these results would not be expected from the disclosures of Bona and Kuchroo. Furthermore, during the interview of March 20, 2000, the Examiner indicated that claims to compositions in which the T cell antagonist is derived from proteolipid protein would be allowable in view of the unexpected results discussed herein and in the accompanying Declaration of Habib Zaghouani.

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In contrast to the permanent elimination of disease symptoms in all of the sick subjects treated with the claimed compositions, the experiments of Kuchroo involved coinjecting healthy animals with a self antigen and a T cell antagonist peptide (as opposed to the immunoglobulins containing a T cell antagonist therein used in the experiments described in the accompanying Declaration) to monitor the development of disease symptoms. Although the procedures of Kuchroo slowed the development of autoimmune disease in healthy animals, half the treated animals in Kuchroo developed autoimmune disease after 25 days (see the lower panel of Figure 4 in Kuchroo). Thus, there is no disclosure or suggestion in Kuchroo that compositions such as the claimed compositions would permanently eliminate disease symptoms in all of the treated subjects.

Furthermore, in contrast to the present compositions, which are designed to suppress immune responses, all of the experiments actually performed by the investigators reviewed in Bona involved the use of immunoglobulins having antigens inserted in the CDR3 regions as vaccines to generate an immune response. While there is some speculation in Bona that self antigens could be inserted into the CDR regions of immunoglobulins to treat autoimmune diseases, there is no disclosure or suggestion in Bona that T cell receptor antagonists could be inserted into immunoglobulins, nor is there any disclosure or suggestion that compositions comprising a T cell receptor antagonist inserted into immunoglobulins could permanently eliminate symptoms in all of the treated subjects.

Because there is no disclosure or suggestion in Bona or Kuchroo that immunoglobulins having T cell receptor antagonists inserted therein could permanently eliminate disease symptoms in all of the treated subjects, the present invention is not obvious over the combination of these references.

III. Rejection of Claims 4, 6, 9, 11, 24, 26, 27, 29, 66-70 and 72-73 Under 35 U.S.C. §112

Claims 4, 6, 9, 11, 24, 26, 27, 29, 66-70 and 72-73 were rejected under 35 U.S.C. §112 on the assertion that they were not supported by the specification. In particular, the Examiner asserted that there was no support for the terminology "known T cell receptor antagonist."

As amended above, the claims recite that the T cell receptor antagonist is derived from proteolipid protein. Accordingly, the above rejection is no longer pertinent to the claims as amended above.

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IV. Conclusion

In view of the foregoing, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of the rejections is respectfully requested. Should the Examiner have any questions regarding this matter he is invited to telephone the undersigned so that the questions may be resolved. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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